Slovak Chamber of Commerce and Industry

MANUFACTURE AND FREE SALE CERTIFICATE NO. 303070

TO WHOM IT MAY CONCERN

UNDERSIGNED AUTHORITY, **SLOVENSKÁ OBCHODNÁ A PRIEMYSELNÁ KOMORA** ***(SLOVAK CHAMBER OF COMMERCE AND INDUSTRY, SCCI),***
a public legal institution from the Law No.9 / 1992 Coll. as amended and revised,
and on the basis of submitted documents

HEREBY CERTIFIES THAT:

1) A company **Chirana Progress, s.r.o.** (hereinafter referred as **MANUFACTURER), headquartered in Vrbovská cesta 17, PIEŠŤANY,** Postcode **921 01, Slovak Republic, is** the limited liability company established under the laws of the Slovak Republic on **January 20, 1998 and** registered with **the District Court Trnava , Section: Sro, Insert No. 10672/T,** with the subject matters: **manufacturing, repairing, distribution and sale of medical devices, instruments and medical supplies.**
2) **MANUFACTURER has its Manufacturing plant in Piešťany (SK).**
3) **Products made in the above Manufacturing plant, which are listed in the Annex of the M&FSC, comply with the requirements and standards for the safety of medical devices as required by applicable legislation of the Slovak Republic and the European Union, i.e.:**
   - **Act no. 355/2007 Coll.** on Protection, Support and Development of Public Health and on Amendments and Supplements to Certain Acts, as amended
   - **Act no. 56/2018 Coll.** on product conformity assessment, making a determined product on the market and on the amendment of certain laws,
   - **Act no. 362/2011 Coll.** on medicines and medical devices and on amendments to certain laws, as amended;
   - **Gov. Regulation no. 582/2008 Coll**. as amended by **2015/2013 Coll.** laying down details on European technical requirements and conformity assessment procedures for medical devices (MDs) **Class II b** under **Annex II of the Medical Device Directive no. 93/42/EEC** and **Directive no. 2011/65/EU;**
4. **The Manufacturing Plant** is the holder of (i) the **Certificate No. Q-0161/18 of Quality Management System** according **ISO 9001:2015** (valid until March 26, 2021), (ii) Certificate **No. M-0102/18 of Medical Devices-Quality Management Systems** according **EN ISO 13485:2016** (valid until March 26, 2021) and (iii) **EC Certificate** No. 2018-MDD/QS-007 **of the Quality Assurance System** (valid until April 16, 2023), according Annex II, Section 3.3, and 5, of the Directive no. 93/42/EEC as amended by Directive 2007/47/EC, all issued by **3EC International a. s., Bratislava,** Slovakia, Notified Body No. 2265 (Reg. No. 305/Q-054 and Q-055, accredited by SNAS).
5) **MANUFACTURER prepared technical documentation, prepared and issued EC Declaration of Conformity for the MDs and affixed with the CE mark under the Medical Device Directive no. 93/42/EEC and therefore the MDs maybe freely sold in all member states of the European Economic Area including the Slovak Republic.**
6) **This Free Sales Certificate for the MDs listed in the Annex is issued to the MANUFACTURER on its request. Export of the MDs outside EU is not prohibited.**

Bratislava, 25 -03- 2019
(Place and date)

SLOVENSKÁ OBCHODNÁ A PRIEMYSELNÁ KOMORA – SLOVAK CHAMBER OF COMMERCE AND INDUSTRY – Certif. Seal

Juraj Knopp
(Name, signature of competent officer of SCCI)

Annex to Certificate of M&FS:

LIST OF MEDICAL DEVICES

of **Chirana Progress, s.r.o., Piešťany**, Slovákia
/MANUFACTURER/

Item:	*List of medical devices (MDs) (product name and Model)*	*MD Reg. no./ SIDC*	*MD Class*	*EC DoC No./ issued:*
1.0	**HYDROTHERAPY EQUIPMENT:**			
1.1.1	LAGUNA, LAGUNA PLUS, LAGUNA BUBBLE, LAGUNA PLUS BUBBLE	P 22650	II. a	EC Declaration of Conformity No. CE-VO-12 according Annex VII of the Directive 93/42 EEC as amended/ Issued by Chirana Progress, s.r.o. on 19.03.2019
1.1.2	LAGUNA TORNADO	P 22654		
1.2.1	OCEAN ECONOMY, OCEAN STANDARD, OCEAN FORTE	P 22654		
1.2.2	OCEAN DE LUXE,	P 22653		
1.3.1	CASCADE, CASCADE PLUS, CASCADE DE LUXE	P 22653		
1.3.2	CASCADE SENIOR	P 26217		
1.4.1	LASTURA	P 26218		
1.4.2	LASTURA PROFI	P 26217		
1.4.3	LASTURA HOBBY	P 22562		
1.5.1	CORAL, CORAL ECONOMY	P 22562		
1.5.2	CORAL LYMFO	P 26215		
1.6.1	HUBBARD BATH; HUBBARD BATH PLUS	P 26215		
1.7.1	VOD 56, VOD 56 HT	P 26216		
1.8.1	NIAGARA, NIAGARA PLUS	P 28886		
1.9.1	ELECTRA, ELECTRA CG	P 10403		
	XXXXXXXX			

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Continue

Annex to Certificate of M&FS:

Item:	*List of medical devices (MDs) (product name and Model)*	*MD Reg. no./ SIDC*	*MD Class*	*EC DoC No./ issued:*
2.0	**Thermotherapy Equipment:**		I.	EC Declaration of Conformity No. CE-VO-12 according Annex VII of the Directive 93/42 EEC / Issued by Chirana Progress, s.r.o. on 19.03.2019 .
2.1	TEP;	P 28471		
3.0	**CHAIRS:**			
3.1	M1, M2., M3;	P 22565		
4.0	**Massage tables:**			
4.1	VOD 47;	P 28483		
5.0	**Accessories:**			
5.1	BUBBLE GRID	P 28482		
5.2	CIRCULAR SHOWER	P 22566		
5.3	SITZ SHOWER	P 22567		
	xxxxxxxxxx			

Ba/25.03.2018/ Ing. J. Knopp, CSc./SOPK/SCCI


Slovens
obchodn
a priemy
komora